

DETAILED ACTION

Status of the Claims

1. Claims 23-30, 32 and 41-45 are pending.

Applicants' amendment and Declaration of Dr. Nigel J. Mouncey filed January 12, 2009 are acknowledged. Applicants' response and Declaration of Dr. Nigel J. Mouncey have been fully considered. Claims 23-30 have been amended, and new claims 41-45 have been added. Therefore, claims 23-30, 32 and 41-45 are examined.

Withdrawn Claim Objections

2. The previous objection to claims 24-29 is withdrawn in view of applicant's amendment to the claims, and applicant's response at page 7 of the remark filed January 12, 2009.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 23-24 and 32 under 35 U.S.C. 112, first paragraph, scope enablement and written description, is withdrawn in view of applicant's amendment to the claims, and applicant's response at pages 7-16 of the remark and Declaration of Dr. Nigel J. Mouncey filed January 12, 2009.

New Claim Objections

4. Claim 32 is objected to because of the use of the term "A production microorganism". Since this microorganism produces riboflavin, use of "A riboflavin production microorganism" is suggested.

New Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 32 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U. S. Patent 6,656,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 32 in the instant application discloses a riboflavin production microorganism which is produced by the method steps of (a) providing a recombinantly produced microorganism from the genus *Bacillus* that has been engineered to contain a polynucleotide sequence which encodes biosynthetic enzymes for riboflavin, and (b) introducing a mutation causing a biotin auxotrophy into the biotin(*bio*) biosynthetic operon of the microorganism to control biomass production and which does not compromise the ability of the microorganism to produce riboflavin. This is obvious variation in view of claim 9 of the patent which discloses a riboflavin production microorganism RB50 containing multiple copies of pRF69, which microorganism is transformed with the polynucleotide sequence of SEQ ID NO:1 (a polynucleotide sequence with a *bioFDB* deletion-insertion mutation). Both sets of claims cite a riboflavin production microorganism, claim 32 of the instant application is directed to a genus of riboflavin production microorganisms, while claim 9 of the patent is directed to a species of riboflavin production microorganism. Thus, claim 32 in present application and claim 9 in the patent are obvious variation of a riboflavin production microorganism.

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Conclusion

6. Claim 32 is rejected; and claims 23-30 and 41-45 are free of art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

March 25, 2009